UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ABDUL NAUSHAD, M.D., and ABDUL NAUSHAD, M.D. P.C., doing business as ADVANCED PAIN CENTERS, Defendants.	)	Case No. 4:24-cv-766

COMPLAINT

Plaintiff, the United States of America (United States), brings this action against Defendants Abdul Naushad, M.D. (Naushad) and Abdul Naushad, M.D. P.C. (Naushad P.C.), doing business as Advanced Pain Centers (APC), seeking: (1) monetary penalties for violations of the Controlled Substances Act (CSA), 21 U.S.C. § 801, *et seq.*; and (2) damages and monetary penalties for violations of the False Claims Act (FCA), 31 U.S.C. § 3729, *et seq.*

JURISDICTION AND VENUE

1. Jurisdiction is based on the civil provisions of the CSA, 21 U.S.C. §§ 842(c)(1)(A), 843(f)(2), and 882(a); the FCA, 31 U.S.C. §§ 3729-3733; and under 28 U.S.C. §§ 1331, 1345, and 1355(a).

2. Venue is proper in the Eastern District of Missouri under 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a) because a substantial part of the events or omissions giving rise to the claims herein occurred in this District.

3. This Court has personal jurisdiction over Naushad, Naushad P.C. and APC (collectively Defendants) because, at all relevant times, they transacted business in this District and Division within Dunklin County, Missouri.

PARTIES

4. Plaintiff is the United States, acting on behalf of the United States Drug Enforcement Agency (DEA), as well as the Department of Health and Human Services (HHS) and, in turn, the Centers for Medicare & Medicaid Services (CMS). The United States administers (a) Medicare, a federally funded health insurance program for the elderly and disabled established by Title XVIII of the Social Security Act (SSA), 42 U.S.C. §§ 1395 *et seq.*; and (b) Medicaid, a federally funded grant program established by Title XIX of the SSA, 42 U.S.C. §§ 1396 *et seq.*, to enable States, including Missouri, to provide medical assistance and related services to indigent and low income persons. At all relevant times, the State of Missouri, through its Department of Social Services (DSS), Missouri HealthNet Division, administered the state-portion of the Medicaid program for indigent patients in Missouri on behalf of and at the direction of the United States.

5. Naushad P.C. was incorporated in 2002 in the State of Missouri and was in the business of providing pain management healthcare services through the corporate APC entity.

6. APC was a corporation formed and registered under the laws of the State of Missouri with its principal place of business at 2865 James Boulevard, Poplar Bluff, Missouri 63901. Between 2005 and 2020, the Defendant owned and operated multiple health care related businesses including a medical testing laboratory and several pain management clinics under the names APC, Advanced Pain Center, or Advanced Pain Centers. At certain times, the Defendant simultaneously owned and operated as many as seven APC clinics in Missouri. The clinics were located in Cape Girardeau, Eureka, Farmington, Festus, Hayti, Kennett, Poplar Bluff, and Sullivan, Missouri. At all relevant times, APC provided medical services to Medicare and Medicaid patients at the APC clinic locations,

including performing urine drug screenings through its medical testing laboratory, owned and operated by APC.

7. At all relevant times to this Complaint, Naushad was a medical doctor licensed to practice medicine in Missouri and the sole owner of Naushad P.C. Naushad held a DEA registration authorizing him to prescribe controlled substances in Schedules II through V of the CSA. At all relevant times to this Complaint, Naushad was owner and the managing employee of APC and, in that capacity, he operated, was a principal of, and exercised control over APC. At certain times relevant to this Complaint, Naushad, through APC, simultaneously owned and operated as many as eight pain management clinics in Missouri. At certain times relevant to this Complaint, Naushad worked as a pain management physician at APC, in addition to his role and duties as the managing employee. At all relevant times to this Complaint, Naushad and other medical doctors and medical professionals employed by APC provided services to Medicare and Medicaid patients at the APC clinic locations and medical testing laboratory. At all relevant times to this Complaint, Naushad provided medical services to Medicare patients and Medicaid patients through Pemiscot Memorial Health Systems, namely at Pemiscot Memorial Hospital and Pemiscot Primary Care clinic, a patient clinic, both located in Hayti, Missouri (collectively Pemiscot).

8. At all relevant times to this Complaint, Naushad resided in St. Louis County Missouri.

THE CONTROLLED SUBSTANCES ACT

9. The CSA and its implementing regulations set forth a comprehensive regulatory regime for the manufacture, distribution, and dispensing of controlled substances. Congress enacted the CSA to facilitate the availability of controlled substances for authorized medical use, while also preventing controlled substances from being diverted out of legitimate channels for illegal purposes. The CSA accordingly establishes a closed regulatory system under which it is unlawful to manufacture,

distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 21 U.S.C. § 841(a)(1).

10. Under the CSA, controlled substances are categorized into five schedules based on several factors, including the substance's medical use, potential for abuse, and safety or dependence liability. *See* 21 U.S.C. § 812.

11. Schedule II drugs have a "high potential for abuse" that may "lead to severe psychological or physical dependence" but nonetheless have a "currently accepted medical use in treatment." 21 U.S.C. § 812(b)(2). Examples include Oxycodone (OxyContin and Percocet), 21 C.F.R. § 1308.12(b)(1)(xiv); Dextroamphetamine-Amphetamine (Adderall), 21 C.F.R. § 1308.12(d)(1); Hydrocodone Bitartrate and Acetaminophen (Vicodin or Norco), 21 C.F.R. § 1308.12(b)(vi); and Fentanyl (Duragesic and Subsys), 21 C.F.R. § 1308.12(c)(9).

12. Schedule III drugs have less potential for abuse than Schedule II drugs but nonetheless may still lead to "moderate or low physical dependence or high psychological dependence." 21 U.S.C. § 812(b)(3). Schedule III drugs have "a currently accepted medical use in treatment." *Id.* Examples include Buprenorphine (Suboxone and Butrans), 21 C.F.R. § 1308.13(e)(2)(i); and Acetaminophen with Codeine, 21 C.F.R. § 1308.13(e)(1).

13. Schedule IV drugs have a lower potential abuse than Schedule III drugs but can have physical or psychological dependence if abused. 21 U.S.C. § 812(b)(4). Examples include Alprazolam (Xanax), 21 C.F.R. § 1308.14(c)(2); Diazepam (Valium), 21 C.F.R. § 1308.14(c)(18); Lorazepam (Ativan), 21 C.F.R. § 1308.14(c)(33); Temazepam (Restoril), 21 C.F.R. § 1308.14(c)(54); Zolpidem (Ambien), 21 C.F.R. § 1308.14(c)(58); and Carisoprodol (Soma), 21 C.F.R. § 1308.14(c)(7).

14. Part C of the CSA requires those who manufacture, distribute or dispense[1] controlled substances, including doctors who write prescriptions for those drugs, to obtain a DEA registration. 21 U.S.C. § 821 *et seq.*; 21 U.S.C. § 822(a). A DEA registrant may only prescribe a controlled substance as "authorized by their registration and in conformity with the other [CSA] provisions." *Id.* at § 822(b).

15. Under Section 842(a)(1) of the CSA, it is unlawful for any person to "distribute or dispense a controlled substance in violation of [21 U.S.C. §] 829." 21 U.S.C. § 842(a)(1). Schedule II through Schedule IV controlled substances may not be prescribed without an effective prescription. 21 U.S.C. § 829(a)-(b). Because it is unlawful to prescribe controlled substances in violation of 21 U.S.C. § 842(a)(1), whose scope is defined by 21 C.F.R. § § 1306.01-1306.27, a violation of these regulations is a violation of federal law. 21 U.S.C. § 842(a)(1).

16. For purposes of the CSA, a prescription is only effective as follows:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.… An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act [21 U.S.C. § 829] and the person knowingly filling such purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. 21 C.F.R. § 1306.04(a)

17. Under Section 842(a)(1), any person who is subject to Part C of the CSA that prescribes a controlled substance in violation of 21 U.S.C. § 829 is subject to a civil penalty for each violation. *See* 21 U.S.C. § 842(a)(1).

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[1] As defined in the CSA, "dispense" means to deliver a controlled substance to an ultimate user and includes the prescribing of a controlled substance. 21 U.S.C. § 802(10). For purposes of consistency, Plaintiff uses the term "prescribe" throughout this Complaint within the meaning of Section 802(10).

THE MEDICAID PROGRAM

18. At all relevant times, the Missouri Medicaid program, jointly funded and operated by the federal and state governments, provided medical benefits to low income beneficiaries living in Missouri.

19. At all relevant times to this Complaint, Naushad and APC were participating Medicaid providers.

20. As Medicaid providers, APC and Naushad agreed to and were required to comply with all the applicable rules and regulations of the Medicaid program, DSS, and HHS. As the managing employee of APC, Naushad knew or should have known that he, through APC, was not entitled to Medicaid payments for claims that did not comply with the applicable rules and regulations, including claims for prescription drugs and diagnostic tests that were not medically necessary.

21. APC through its agents and employees, including Naushad, submitted claims for Medicaid beneficiaries who were listed as his and APC's patients to DSS and its fiscal intermediaries for adjudication, processing and payment.

22. Pemiscot through its agents and employees, including Naushad, submitted claims for Medicaid beneficiaries who were listed as patients of Naushad through Pemiscot to DSS and its fiscal intermediaries for adjudication, processing and payment.

THE MEDICARE PROGRAM

23. Congress established the Medicare program to provide health insurance coverage for people age 65 or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 426, 426a.

24. The Medicare program consists of four parts: A, B, C, and D. Defendants submitted, or caused to be submitted, claims under Medicare Part A, B and C.

25. Medicare Part A provides inpatient services for aged and disabled recipients. 42 U.S.C. §§ 1395c-1395i-6. Medicare Part B provides medically necessary services to beneficiaries for diagnosis

and treatment, including laboratory tests, physician visits and other outpatient care. 42 U.S.C. §§ 1395j-1395w-6. Medicare part C is comprised of private healthcare insurers who contract with Medicare to offer medical coverage, a portion of which is paid by Medicare. 42 U.S.C. § 1395w-22.

26. All participants and medical providers must agree to comply with the standards and terms and conditions of payment governing the Medicaid program. *See* 42 U.S.C. § 1395f.

27. Medicare only covers drugs that (a) are used for a medically accepted indication – i.e. a use that is approved under the Food, Drug, and Cosmetic Act (FDCA) at 21 U.S.C. § 301, *et seq.*; or (b) the "use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i)." *See* 42 U.S.C. §§ 1396r-8(g)(1)(B)(i) & (k)(6); 42 C.F.R. § 423.100. The referenced compendia in subpart (b) consists of the following sources: the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (or its successor publications); and the DRUGDEX Information System. 42 U.S.C. § 1296r-8(g)(1)(B)(i)(I)-(III).

28. Prescriptions for controlled substances that are not issued for a legitimate medical purpose, such as for recreational use, are not for "medically accepted indications" and are not covered Medicare Part D drugs. *See* 42 U.S.C. § 1395w-102(e)(1).

29. Prescriptions for controlled substances that are not issued for a legitimate medical purpose, such as for recreational use, are not "valid prescriptions" and are not covered Medicare Part D drugs. 42 C.F.R. § 423.104(h).

30. Medicare Part B covers medical services that are "reasonable and necessary," including the prescribing of "valid prescriptions." *See* 42 U.S.C. § 1395y(a)(1)(A).

31. Medicare regulations state that it will not approve laboratory tests that are not reasonable and necessary, including diagnostic lab tests, such as urinalyses. 42 C.F.R. §§ 410.32(a), (d)(3)(ii); *see also* 42 U.S.C. § 1395y(a)(1)(A).

32. At all relevant times to this Complaint, Naushad and APC were Medicare providers issuing non-valid prescriptions and were billing Medicare for issuing the non-valid prescriptions.

33. At all relevant times to this Complaint, Naushad and APC were Medicare providers ordering and at times providing diagnostic urinalysis that were medically unnecessary and were billing Medicare for such diagnostic tests.

34. APC through its agents and employees, including Naushad, submitted prescription claims to CMS and its fiscal intermediaries for Medicare Part A, B, C and D beneficiaries for adjudication and payment.

35. Pemiscot through its agents and employees, including Naushad, submitted prescription claims to CMS and its fiscal intermediaries for Medicare Part A, B, C and D beneficiaries for adjudication and payment.

36. As a Medicare provider, and the managing employee of APC, Naushad knew or should have known that he, individually, and that APC and its agents were not entitled to Medicare payments for issuing prescriptions that did not comply with Medicare's applicable rules and regulations, including claims for prescribing prescriptions drugs that were not medically necessary.

37. As a Medicare provider and the managing employee of APC, Naushad knew or should have known that he, individually, and that APC and its agents were not entitled to Medicare payments for ordering and/or performing diagnostic tests that did not comply with Medicare's applicable rules and regulations, including claims for ordering and/or performing diagnostic tests that were not medically necessary.

FACTUAL BACKGROUND

I. WRONGFUL PRESCRIBING.

38. As an outpatient pain management clinic, APC prescribed controlled substances to patients. At all relevant times to this Complaint, APC was registered with the DEA as a pain management clinic to dispense CSA Schedules II through V controlled substances.

39. At all relevant times to this Complaint, as the managing employee of APC, Naushad had the control and authority to effect APC and its agents and employees' compliance with the CSA and the FCA.

40. The Centers for Disease Control and Prevention (CDC) recommends caution when using opioids at any dosage, carefully reassessing the risks and benefits of opioids when morphine milligram equivalents (MMEs) are 50 or higher and avoiding or carefully justifying dosages of 90 MMEs or higher.

41. Defendants failed to detect and address indicators of drug diversion, known in the pharmacy industry as "red flags," indicating that certain prescriptions were not legitimate. For example, Defendants disregarded numerous instances in which the prescribed controlled substances grossly exceeded safe prescription combinations; disregarded instances where controlled substances were being prescribed to patients with a history of substance abuse; disregarded instances where controlled substance combinations that could potentially cause depression of the central nervous system (CNS) were prescribed to patients; and disregarded instances where controlled substances were prescribed to patients that were medically unnecessary.

42. Defendants also prescribed prescriptions for opioids to patients at the same time as other medications that, when used in combination, are known to dangerously increase the opioid-produced euphoric high and increase the risk of respiratory depression, cardiac depression, overdose, and death. Such medications are known as opioid "potentiators." Benzodiazepines, for example, are

a class of drugs commonly known to be opioid potentiators; because of this, the CDC discourages use of benzodiazepines simultaneously with opioids.

43. Defendants routinely dispensed a combination of drugs colloquially known as the "holy trinity." The "holy trinity" is a term used to describe the following combination of prescribed controlled substances: a benzodiazepine (such as Alprazolam), an opioid (such as Hydrocodone), and a muscle relaxant (such as Carisoprodol). This combination poses danger because the drugs depresses the central nervous system and respiration, reducing the ability to breathe.

44. Naushad, through Pemiscot and APC and other providers employed by APC, regularly prescribed controlled substances to patients simultaneously with non-controlled substances, such as Gabapentin and Tizanidine that are known to enhance the addictive, euphoric effects of the opioids and, as a result, are commonly sought-after in combination with opioids by individuals with substance abuse disorders and individuals who seek to use opioids recreationally.

45. Based on these red flags, Defendants knew or should have known that the prescriptions they issued were invalid and not used for a medically accepted indication, but nonetheless they submitted or caused to be submitted claims for their reimbursement to the Medicaid and/or Medicare federal healthcare programs. If Medicaid and/or Medicare had known that these prescriptions were invalid, they would not have paid for them.

46. The prescription of a controlled substance in the face of the warning signals described above, without first ensuring the prescription was issued for a legitimate purpose by a practitioner acting in the usual course of professional practice, violates the CSA.

47. Submitting or causing the submission of claims to the Medicaid and/or Medicare federal healthcare programs for medications (whether scheduled controlled substances or not) in the face of the warning signals described above, without first ensuring the prescriptions are valid and medically necessary, violates the FCA.

II. URINE DRUG SCREENINGS.

48. From at least as early as in or about 2018 to at least as late as 2019, Naushad and other providers at APC engaged in a practice of ordering unreasonable and medically unnecessary urine drug tests that were not used by Naushad or other providers at APC in the management of the patients' medical conditions.

49. Presumptive drug tests (also known as qualitative drug tests) are used to detect the presence or absence of a drug or drug class. It is reasonable and necessary to conduct presumptive drug tests only for the existence of drugs most likely to be present based on the patient's medical history, current clinical presentation and illicit drugs in common use.

50. APC and Naushad routinely conducted panels of presumptive (qualitative) drug tests that (a) included prescription drugs for which patients were not prescribed and (b) failed to include drugs for which patients were prescribed. The panels routinely tested for illicit drugs, notwithstanding that, according to APC's medical records, the patients were clinically presenting as oriented, awake, alert, and/or cooperative, without any noted historical or community risk factors for illicit drug use.

51. A definitive drug test (also known as a quantitative drug test) identifies specific substances (i.e. drugs, metabolites) and can be used to confirm inconsistent test results. It is reasonable and necessary to administer a definitive (quantitative) drug test after a presumptive (qualitative) drug test when that presumptive (qualitative) drug test has an inconsistent result.

52. According to guidelines in effect at the time, diagnostic urine testing is covered under the Medicare/Medicaid regulations when medically necessary, supported by documentation evincing the medical necessity of the drug test ordered and the clinical indicators based on a risk assessment that led to the test ordered.

53. Only one presumptive (qualitative) drug test may be billed per patient per date of service (DOS) and one definitive (quantitative) drug test may be billed per patient per date of service.

54. Physicians are expected to determine the medical necessity for definitive (quantitative) drug testing in light of a positive test result and document that necessity in the medical record. Where a presumptive (qualitative) drug test is positive or negative inconsistent for the medication prescribed to the patient, a physician may perform a definitive (quantitative) drug test; however, the presumptive (qualitative) drug test must be performed first to determine such results.

55. Contrary to these guidelines, Naushad, APC and its agents routinely conducted both presumptive (qualitative) and definitive (quantitative) drug tests on patients at the same time. More specifically, it was Naushad and APC's protocol to conduct definitive (quantitative) drug tests simultaneously with presumptive (qualitative) drug tests even when that presumptive (qualitative) drug tests had a consistent result with the patient's medication history. There were no specific orders from a physician or other medical professional for the definitive (quantitative) drug tests.

56. Naushad and APC routinely failed to use the drug test results – both presumptive (qualitative) and definitive (quantitative) – in the management of patients' medical conditions, even when patients test results indicated they were non-compliant with the prescribed regimen and/or using controlled substances outside of the prescribed regimen.

57. The drug tests were knowingly not reasonable or medically necessary and, therefore, were falsely submitted for reimbursement to Medicare and Medicaid in violation of the FCA.

III. SPECIFIC CSA AND FCA VIOLATIONS.

58. Defendants violated the CSA by unlawfully prescribing controlled substances that had no legitimate medical purpose and that were outside the usual course of professional practice in violation of the CSA. *See* 21 U.S.C. §§ 829, 824; 21 C.F.R. §§ 1306.04.

59. Defendants violated the FCA by submitting or causing to be submitted false claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (Medicare); and the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (Medicaid) for invalid and

medically unnecessary prescriptions and medically unnecessary diagnostic urinalyses screenings. *See* 31 U.S.C. § 3729.

60. Accordingly, the United States has a right to civil claims against APC and Naushad arising from the conduct set forth in the paragraphs below in accordance with 31 U.S.C. § 3729, *et seq.*, and 21 U.S.C. § 843(f)

A. DEFENDANTS UNLAWFULLY PRESCRIBED CONTROLLED SUBSTANCES AND, IN DOING SO, VIOLATED THE CSA, THE FCA OR BOTH.

1. SPECIFIC PATIENT CARE.

a. PATIENT D.C.: CSA AND FCA VIOLATIONS.

61. D.C. was a patient of Naushad's from February 2018 to November 11, 2020.

62. While D.C. was under Naushad's care, Naushad and other APC's employees wrote controlled substance prescriptions to him every month from February 2018 through November 2020 that had no legitimate medical purpose and were outside the usual course of professional practice.

63. For instance, from February 2018 to November 2020, Naushad repeatedly prescribed Hydrocodone to D.C. notwithstanding multiple warning signs that he was abusing the drug. The warning signs during this time period included several aberrant urine drug test results where D.C. (a) repeatedly tested negative for Hydrocodone, suggesting that he was either consuming the drug too quickly or was diverting it altogether; or (b) tested positive for opioids that neither Naushad nor others at APC had prescribed him, including Oxycodone and Hydromorphone.

64. On some occasions between February 2018 and November 2020, Naushad continued to fill D.C.'s Hydrocodone prescriptions without seeing him and despite inconsistent urinary drug screenings. For example, in June, July and August 2018, Naushad issued Hydrocodone prescriptions to D.C. without ever seeing him.

65. In November 2018, D.C. presented unresponsive to Pemiscot Memorial Hospital (where Naushad practiced and could access patient medical records). Emergency medical personnel had to manually resuscitate D.C. and administered Narcan due to a drug overdose. Naushad continued to prescribe D.C. Hydrocodone after this incident.

66. From March 2018 to November 2020, Naushad frequently prescribed Hydrocodone to D.C., notwithstanding his physical presentation during medical exams. For instance, on January 16, 2020, D.C. was falling asleep during an exam. His speech was slurred, his eye were bloodshot and his thoughts were "broken." Nonetheless, he was prescribed Hydrocodone.

67. Naushad continued to prescribe Hydrocodone to D.C. throughout 2020 despite D.C's continued inconsistent urine drug tests and his continued abuse of prescribed and non-prescribed controlled substances. For instance, on November 17, 2020 D.C. saw Naushad at Pemiscot Memorial Hospital for a lumbar injunction. At that visit, Naushad prescribed D.C. a twenty-eight day supply of Hydrocodone to him.

68. Three days later on November 20, 2020, D.C. died due to a "probable overdose of prescription medication."

B. PATIENT C.B.: FCA VIOLATIONS.

69. Naushad began prescribing Hydrocodone to C.B. at his Pemiscot Primary Care practice in September 2018.

70. From on or about September 2018 to on or about December 2018, Defendants provided prescriptions to C.B. that were not issued for a legitimate medical purpose and outside the usual course of professional practice in violation of the CSA. These drugs were all FDA-approved prescription medications. Defendants billed these prescriptions to Medicare, Medicaid or both.

71. Defendants specifically prescribed medication to C.B., which when combined, resulted in combinations that posed significant health risks. In multiple instances, Defendants issued the "holy

trinity" to him – i.e., Hydrocodone-Acetaminophen, Alprazolam (a benzodiazepine) and Cyclobenzaprine HCL (a muscle relaxer). Prescribing this combination of medications was particularly problematic given that C.B. had COPD, emphysema and high blood pressure; and the prescriptions, when combined, act as a respiratory depressant.

72. Naushad also failed to consider C.B.'s subjective complaints in prescribing him medication. For instance, during an exam in October 2018 with a nurse practitioner, C.B. reported "mood swings" that included feeling "happy one minute" and then "crying depressed with thoughts of suicide." During this visit, C.B. reported feeling down, depressed, or hopeless "nearly every day," and indicated that "the pain is worse than ever" and that he "just wants it to go away." Nonetheless, Naushad refilled C.B.'s Hydrocodone prescription on October 11, 2018.

73. Naushad equally disregarded the results of C.B.'s urine drug screening tests. On October 11, 2018, Naushad ordered a urine drug screen. Those results were reviewed at C.B.'s November 2018 medical exam. The October 18th results contained a positive hit for methamphetamine (meth). Naushad signed a progress note acknowledging that C.B. was positive for "meth" and had received a verbal warning; however, however, Naushad prescribed him Hydrocodone on November 8, 2018.

74. On December 6, 2018, Naushad terminated C.B. from his practice because he again tested positive for meth. Yet at the same visit, Naushad wrote C.B. another prescription for a 28-day supply of Hydrocodone.

75. Just two days later on December 8, 2018, C.B. died due to an overdose of his prescription medications.

c. PATIENT J.M.: FCA VIOLATIONS.

76. Naushad treated J.M. from approximately April 2018 through March 2019 at Pemiscot Primary Care practice and intermittently at Pemiscot Memorial Hospital.

77. J.M. had a documented history of psychological issues and substance abuse. Throughout 2015 and 2016, he sought medical treatment for both. For instance, J.M. repeatedly reported hearing voices, suffered from hallucinations and had suicidal ideation. On February 6, 2015, he was admitted to Pemiscot Memorial Hospital for psychosis, reporting that he was "hearing voices in his head telling him God and the devil are fighting for his soul."

78. About eight months later on October 9, 2015, J.M. was again admitted to Pemiscot Memorial Hospital for hallucinations. He reported "frequent" and "daily" suicidal ideation. That same day, J.M. was referred to Resolutions Behavioral Health, a Pemiscot Memorial Hospital affiliate. After a psychological exam, in which J.M. admitted to abusing "a lot of pills as a kid," eating "a lot of Xanax in [his] 20s," and taking Hydrocodone, he was diagnosed with "[p]rescription medication abuse" with a recommendation to "significantly minimize" his substance use.

79. Dr. Abdullah Arshad, a physician at Pemiscot Memorial Hospital, referred J.M. to Naushad for pain management at Pemiscot Primary Care Center on March 25, 2018.

80. Naushad first saw J.M. at Pemiscot Primary Care Center on April 6, 2018. During that first visit, J.M. informed Naushad that he recently took Ultram, a narcotic painkiller. His urine drug test taken that same date came back with an "F11.20" – "opioid dependence" – and J.M. tested positive for benzodiazepines, opiates and tricycle antidepressants. Nonetheless, Naushad prescribed J.M. with Hydrocodone on April 6, 2018.

81. Naushad repeatedly prescribed J.M. with Hydrocodone and Oxycodone from 2018 to 2019, disregarding multiple warning signs indicating that J.M. was abusing or diverting both medications. These warning signs included clear annotations in J.M.'s medical records that he had abused prescription medication. For instance, J.M's July 27, 2018 medical records contained a note to "watch this pt [patient]." Yet, Naushad prescribed him with Hydrocodone on July 27, 2018.

82. J.M.'s urine drug tests thereafter returned inconsistent and positive for Ultram. He received a verbal warning on August 24, 2018. Yet on September 21, 2018, Naushad again wrote him another prescription for Hydrocodone.

83. The final warning signs included multiple aberrant drug test results from or about April 2018 to on or about February 2019 where J.M. either (a) tested at increased levels for his prescribed Hydrocodone and was therefore consuming it too quickly; (b) tested positive for medications that neither Naushad or others at APC had prescribed, indicating substance abuse; or (c) were overall inconsistent. For example, Naushad saw J.M. on February 7, 2019 at Pemiscot Memorial Hospital for a lumbar injection. During that visit, Naushad ordered a drug test which came back positive for benzodiazepines, opiates, antidepressants, anticonvulsants, and cotinine but negative for J.M.'s prescribed Oxycodone. Naushad received a copy of the drug screening report and initialed the test results as consistent even though they were actually inconsistent.

84. A month later on March 7, 2019, Naushad treated J.M. for another lumbar injection and prescribed him twenty-eight days of Oxycodone that day notwithstanding the prior inconsistent drug screening results.

85. On March 9, 2019, J.M. died due to an overdose of opiates and benzodiazepines.

d. PATIENT P.N.: FCA VIOLATIONS.

86. From on or about December 2017 to about August 2018, Defendants prescribed drugs to P.N. while disregarding red flags indicating that those prescriptions had no legitimate medical purpose and were outside the usual course of professional practice in violation of the CSA.

87. Defendants further billed P.N.'s prescriptions to Medicare, thereby implicating FCA liability. Based on the red flags described below, Defendants knew that P.N.'s prescriptions were not used for a medically accepted indication and lacked a legitimate medical purpose. If Medicaid and Medicare had known that these prescriptions were invalid, they would not have paid for them.

88. P.N. was a patient at APC from approximately December 2017 through August 2018. She saw Naushad for pain management starting on December 1, 2017.

89. P.N. had a history of mental health issues, including depression, anxiety, bi-polar disorder, and schizophrenia. She had a prior hospitalization at Resolutions Behavioral Health, a subsidiary of Pemiscot Memorial Hospital. When she came to APC on November 8, 2017, P.N. was already taking Xanax 4mg/day, Diazepam and Oxycodone.

90. P.N. had a history of substance abuse. She received treatment at Pemiscot Memorial Hospital for multiple drug overdoses in 2017, as well as for a suicide attempt on August 26, 2016 using Tramadol (Ultram), Xanax, Oxycodone/Tylenol tablets and Soma.

91. P.N. was again admitted to Pemiscot Memorial Hospital for a drug overdose on August 21, 2017. On that date, she admitted to using meth two days before her admission. She was given a urine drug test that day which tested positive for amphetamines, benzodiazepines, opiates, phencyclidine (PCP), and meth.

92. Despite this medical history, Naushad and other APC employees prescribed P.N. with dangerous combinations of medication throughout 2018: (a) from February 2018 through August 2018, Naushad repeatedly prescribed her Norco (Hydrocodone-Acetaminophen), Gabapentin and Tizanidine HCL while she was already taking Latuda, Desvenlafaxine Succinate ER and Doxepin HCL; and (b) on May 11, 2018, Naushad prescribed her Narcan while she was already taking Oxycodone, Tizanidine HCL, Gabapentin, Latuda, Desvenlafaxine Succinate ER and Doxepin HCL

93. P.N. provided several inconsistent drug test results from April 2018 to August 2018 while being treated by Naushad. For example, on April 13, 2018, she had negative results for metabolites of her prescribed medication and increased levels of Oxycodone beyond her prescription levels. Naushad, nonetheless, prescribed her a higher dosage for Oxycodone, as well as for Tizanidine HCL and Gabapentin that day.

94. On June 6, 2018, P.N. had another inconsistent drug test and, as a result, received a verbal warning at her next exam on July 11, 2018 to take her medication as prescribed. Dr. Naushad indicated that APC's relationship with P.N. would be terminated if her urine test was again low.

95. The next month on August 15, 2018, P.N. had a negative urine drug test for Oxycodone. Despite her prior inconsistent drug test results, verbal warning and the possibility of having her doctor-patient relationship ended, Naushad prescribed her with Oxycodone, Gabapentin, Tizanidine HCL, and Meloxicam on August 15, 2018.

96. Five days later on August 20, 2018, P.N. died due to "mixed drug intoxication."

E. PATIENT D.F.: FCA VIOLATIONS.

97. D.F. was a patient of Defendants from around November 2014 to September 2018.

98. When she first came to APC in 2014, D.F. was already taking Xanax 1 mg three times a day; Norco 5-325 mg one to two doses every 6 hours; and Zolpidem 5 mg one time per day. During her initial visit in November 2014, staff performed a urine drug test. Without receiving the results of that test, Defendants prescribed Gabapentin to D.F. and increased her Norco prescription.

99. On December 9, 2014, having only seen D.F. on one occasion, Defendants tripled her Gabapentin dosage from 100 mg three times a day to 300 mg three times a day. D.F. was advised to monitor her sleepiness due to the increased dosage amount; however, she did not return to APC for treatment for seven months.

100. D.F. returned to APC for treatment in July 2015. Her reaction to the increased Gabapentin dosage from December 2014 was not noted. However, Defendants continued to treat her from July 2015 through September 2015 with Gabapentin and Norco. After September 2015, D.F. did not return to APC for another six months.

101. In March 2016, D.F. returned for treatment at which point Defendants resumed Gabapentin, Zanaflex and Norco.

102. In 2016, D.F. reported that she suffered from asthma, COPD, shortness of breath, wheezing, cough and chest pain. She also admitted to using recreational drugs.

103. Two years later in June 2018, D.F.'s COPD was diagnosed as "severe" and, as a result, it was recommended that she not have neck pain surgery because there was a "significant" possibility that she would not come off a ventilator. This COPD diagnosis was referred to APC and discussed with D.F. during a July 23, 2018 medical exam.

104. Despite D.F.'s medical history and drug use, Naushad and other APC employees prescribed controlled substances to her from November 2014 through September 2018 that had no legitimate medical purpose and outside the usual course of professional practice.

105. Further, Defendants billed D.F.'s prescriptions to the Missouri Medicaid healthcare program, thereby implicating FCA liability. Defendants knew, however, that D.F.'s prescriptions were not used for a medically accepted indication and lacked a legitimate medical purpose. If Medicaid had known that these prescriptions were invalid, it would not have paid for them.

106. For example, Defendants issued prescriptions to D.F. that when combined resulted in dangerous combinations that posed significant health risks. Specifically, Defendants prescribed her the "holy trinity" – i.e., Hydrocodone-Acetaminophen, Zanaflex/Tizanidine and Alprazolam. Prescribing the "holy trinity" was particularly problematic given D.F.'s COPD because these prescriptions, when combined, act as a respiratory depressant.

107. At other times during his treatment of D.F., Naushad prescribed D.F. with other dangerous drug combinations. For example, from October 2015 through September 2018, Naushad prescribed her Norco, Zanaflex/Tizanidine and Gabapentin while D.F. was taking Xanax. On April 30, 2018, Naushad prescribed her Oxycodone, Tizanidine HCL, Gabapentin and Narcan.

108. Defendants further ignored other warnings signs during D.F.'s treatment. For example, D.F. presented several aberrant urine drug test results between 2015 and 2018 where she

either (a) tested low or negative for her prescribed Hydrocodone and was therefore either consuming it too quickly or was diverting it altogether; or (b) tested positive for medications that neither Naushad or others at APC had prescribed, indicating D.F. was abusing prescription drugs. Despite these repeated inconsistent urinary drug test results – many of which were noted in D.F.'s medical records with warnings – Defendants issued her Hydrocodone.

109. Between 2016 and 2018, Naushad repeatedly increased D.F.'s prescription dosages based on D.F.'s demands. For example, in April 2016, Defendants increased her Gabapentin dosage even though there had been long absences with her medical exams. In June 2016, Naushad increased D.F.'s Gabapentin dosage yet again, raising it to six times the originally prescribed amount.

110. In July 2016, D.F. complained that the Gabapentin dosage made her drowsy and, as a result, her prescription was lowered to 400 mg three times a day. However, Defendants subsequently increased the dosages in August and September 2017.

111. In an April 2018 exam, D.F. indicated that she only took half of her Gabapentin. Naushad, however, did not lower D.F.'s dosage for that medication.

112. D.F. made similar requests to increase her Hydrocodone dosages during this time period. For example, at a February 2018 exam, D.F. requested a dosage increase. Defendants noted that D.F. had presented inconsistent urine drug tests but, rather than terminating the patient relationship, D.F. was given a prescription for Gabapentin, Zanaflex and Norco.

113. Two months later on April 2, 2018, D.F. again requested a Hydrocodone increase and, despite prior concerns about her usage, Naushad increased the dosage.

114. Twenty-eight days later on April 30, 2018, D.F. again asked for an increase. Naushad noted that D.F.'s prescription would be increased on the next visit if she presented a consistent urine drug test result. That drug test, dated April 30, 2018, was inconsistent; however, Naushad increased D.F.'s Hydrocodone dosage to 5-325 mg three times daily at the next visit on May 29, 2018. Some

two months later on July 23, 2018, Naushad again increased D.F.'s Hydrocodone dosage to 7.5-325 mg three times a day.

115. Further, on other occasions, Naushad and other APC employees disregarded D.F.'s subjective complaints about her medical conditions and prescribed her drug combinations that posed a significant risk to her health. On September 7, 2018, for instance, D.F. called APC requesting additional pain medication. She reported being diagnosed with pneumonia, sleeping for six days without eating or drinking. She was taking extra pain medication during this time, had none and, therefore, requested a refill before her scheduled exam on September 17, 2018.

116. On September 17, 2018, D.F. reported that she had been hospitalized for "breathing" problems. Nonetheless, Naushad prescribed D.F. Norco, Gabapentin and Zanaflex/Tizanidine.

117. Two days later on September 19, 2018, D.F. died due to "mixed drug intoxication."

2. APC HAD EGREGIOUS RECORD KEEPING.

118. Naushad and APC, through Naushad and other medical doctors employed by APC, prescribed controlled substances to patients without seeing them, thereby violating the CSA because they issued prescriptions that were without a legitimate medical purpose and outside the usual course of professional practice

119. Moreover, Naushad and APC, through Naushad and other medical doctors employed by APC, caused claims for these controlled substances to be submitted for reimbursement to Medicare and Medicaid. As a result, Naushad and APC caused false claims to be paid by the United States in violation of the FCA.

120. APC's medical records show a failure to conduct proper medical evaluations where Naushad and other APC employees either failed to fully assess a patient or never saw a patient at all before prescribing opioids. For example, D.C.'s medical records between June 22, July 20 and August

17, 2018 show that no vitals were taken and no systems reports and patient history were documented. Nonetheless, D.C. was issued prescriptions for Hydrocodone.

121. Similarly, on October 17, 2018, J.M. was a "NO SHOW" for his appointment. His failure to appear was noted in his medical records. Naushad, however, issued him a Hydrocodone prescription on that date. The same thing happened on November 13, 2018, when J.M. failed to appear for an appointment but received a prescription for Hydrocodone anyway.

122. With some patients, the records are strikingly similar from one date-of-service to another. For example, D.F.'s medical records between July and September 2018 were simply copied and pasted from entry to the next. Her medical records in January and February 2019 are the same.

3. PATIENT DEATHS.

123. Naushad and APC failed to conduct risk evaluations for the above-referenced patients to determine whether they were likely to abuse or misuse their prescribed medications or any illicit substances, and Naushad and APC continued to prescribe controlled substances to these patients while ignoring urine drug test results indicating that the patients were taking controlled substances outside of their prescribed regimen.

124. In doing so, Defendants accordingly prescribed controlled substances to many patients only a handful of days before they died from an overdose or drug-related indication, including as described above, C.B., D.C, J.M., P.N., and D.F.

125. As a result of Defendant's improper patient care, Naushad, APC through Naushad and other medical doctors employed by APC prescribed controlled substances without a legitimate medical purpose while acting outside the usual course of professional practice, thereby violating the civil provisions of the CSA as described above.

126. Moreover, as a result of Defendant's improper patient care, Naushad, APC through Naushad and other medical doctors employed by APC submitted or caused to be submitted claims

for these controlled substances to Medicare and Medicaid. In doing so, Defendants violated the FCA as described above.

B. DEFENDANTS ORDERED MEDICALLY UNNECESSARY URINE DRUG SCREENINGS THAT THEY BILLED TO MEDICARE AND VIOLATED THE FCA.

127. Between 2018 and 2019, Defendants, through its lab owned and operated by APC, simultaneously conducted definitive (quantitative) urinalysis screenings along with presumptive (qualitative) urinalysis screenings for their patients against established guidelines and billed Medicare and/or Medicaid for the same.

128. Medicare guidelines provide that definitive (quantitative) testing is only reasonable and medically necessary if presumptive (qualitative) test results are inconsistent with treatment and bear a negative or positive finding. The need for definitive (quantitative) testing, therefore, is dependent upon a positive or negative result on a presumptive (qualitative) test.

129. Defendants' drug testing were performed on-site, which would have enabled them and their providers to know the results of presumptive (qualitative) testing on the date of service.

130. Nonetheless, Defendants ordered both presumptive (qualitative) and definitive (quantitative) urinary drug screenings at the same time and a definitive (quantitative) test was requested absent first receiving or reviewing a presumptive result. The urinalyses were performed simultaneously without prior determination of the medical need for a follow-up test.

131. In doing so, Defendants regularly billed Medicare and Medicaid for presumptive (qualitative) and definitive (quantitative) drug tests on the same date of service.

132. Between February 1, 2018 and June 27, 2019, Defendants billed Medicare and were subsequently paid approximately $317,160.16 for definitive (quantitative) urine drug screenings.

1. UDS TESTS WERE NOT UTILIZED IN PATIENT CARE

133. In addition to other billing criterion, a diagnostic test is considered reasonable and necessary if the results of that test are used in the management of the beneficiary's medical care. 42 C.F.R. § 410.32(a).

134. From February 1, 2018 through June 27, 2019, Naushad and APC falsely indicated in reimbursement claims to Medicare and Medicaid using CPT and HCPCS codes 80307, 80307AR, 80307SA, G0431, G6042, G6053, G6056, G6058, G0479, G0480AR, G0480SA and G0480 that the urine drug tests being performed were reasonable and medically necessary for patients being prescribed controlled substances, when the results of the urine tests were not being utilized for the treatment or care of the patient.

135. For example, those urine drug screening tests described in this part include, but are not limited to, the following patients:

A. D.C.

136. During the course of D.C.'s treatment, Defendants simultaneously performed both definitive (quantitative) and presumptive (qualitative) urinalysis drug tests on the following dates:

a. February 2, 2018 – inconsistent results;

b. March 2, 2018 – inconsistent results;

c. March 30, 2018;

d. November 9, 2018 – inconsistent results;

e. January 8, 2019 – inconsistent results;

f. March 8, 2019 – inconsistent results; and

g. May 7, 2019 – inconsistent results (negative for secondary metabolite).

137. The dual urinalysis tests that Defendants simultaneously performed on D.C. would have provided Defendants with a presumptive result (testing for the presence of a drug) and a definitive result (testing for the amount/level of a drug).

138. Although performed in-house at APC, the urine drug tests results were often not received or reported in a timely manner and the results of the urine tests ordered and performed by Defendants were not utilized for the treatment or care of patients, or to determine the appropriateness of continued prescriptions for opioids and/or narcotics.

139. Absent the prerequisite of first receiving a presumptive result, a review of the urine tests would have aided Defendants in determining the proper course of treatment for D.C., including reducing, minimizing or eliminating prescriptions for controlled substances in the face of inconsistent urine test results. Nonetheless, Defendants routinely ordered both definitive (quantitative) and presumptive (qualitative) urinalysis drug tests.

140. Despite repeated inconsistent results throughout March 2018 to November 2020 – including, but not limited to, testing negative for his prescribed Hydrocodone (January 2019, October 2019, November 2019), testing positive for non-prescribed Oxycodone (March 2018) and testing inconsistent for non-prescribed Hydromorphone (October 2020) – Defendants as described above in Paragraphs 61-68 continued to issue prescriptions to D.C. for opioids and/or narcotics until he ultimately died of an overdose.

141. Defendants billed Medicare/Medicaid for the urine drug screenings, which they did not utilize in the care and treatment of patients.

B. P.N.

142. During the course of P.N.'s treatment, Defendants simultaneously performed both definitive (quantitative) and presumptive (qualitative) urinalysis drug tests on the following dates:

a. April 13, 18 – inconsistent results;

b. June 6, 2018 – inconsistent results; and

c. August 15, 2018 – inconsistent results.

143. The dual urinalysis tests that Defendants simultaneously performed on P.N. would have provided Defendants with a presumptive result (testing for the presence of a drug) and a definitive result (testing for the amount/level of a drug).

144. Although performed in-house at APC, the urine drug tests results were often not received or reported in a timely manner and the results of the urine tests ordered and performed by Defendants were not utilized for the treatment or care of patients, or to determine the appropriateness of continued prescriptions for opioids and/or narcotics.

145. Absent the prerequisite of first receiving a presumptive result, a review of the urine tests would have aided Defendants in determining the proper course of treatment for P.N., including reducing, minimizing or eliminating prescriptions for controlled substances in the face of inconsistent urine test results. Nonetheless, Defendants routinely ordered both definitive (quantitative) and presumptive (qualitative) urinalysis drug tests.

146. Despite repeated inconsistent results throughout 2018 – including, but not limited to, testing at increased levels for prescribed Oxycodone (April 2018), testing negative for metabolites of prescribed Oxycodone (June 2018) and testing negative for prescribed Oxycodone altogether (August 2018) – Defendants as described above in Paragraphs 88-96 continued to issue prescriptions to D.C. for opioids and/or narcotics until she ultimately died of an overdose.

147. Defendants, however, billed Medicare/Medicaid for the urine drug screenings, which they did not utilize in the care and treatment of patients.

c. D.F.

148. During the course of D.F.'s treatment, Defendants simultaneously performed both definitive (quantitative) and presumptive (qualitative) urinalysis drug tests on the following dates:

a. April 2, 2018;

b. April 30, 2018 – inconsistent results; and

c. July 23, 2018 – inconsistent results.

149. The dual urinalysis tests that Defendants simultaneously performed on D.F. would have provided Defendants with a presumptive result (testing for the presence of a drug) and a definitive result (testing for the amount/level of a drug).

150. Although performed in-house at APC, the urine drug tests results were often not received or reported in a timely manner and the results of the urine tests ordered and performed by Defendants were not utilized for the treatment or care of patients, or to determine the appropriateness of continued prescriptions for opioids and/or narcotics.

151. Absent the prerequisite of first receiving a presumptive result, a review of the urine tests would have aided Defendants in determining the proper course of treatment for D.F., including reducing, minimizing or eliminating prescriptions for controlled substances in the face of inconsistent urine test results. Nonetheless, Defendants routinely ordered both definitive (quantitative) and presumptive (qualitative) urinalysis drug tests.

152. Despite repeated inconsistent results throughout 2015 to 2018 – including, but not limited to, testing negative for prescribed Clonazepam (July 2015), testing positive for non-prescribed Tramadol (June 2017) and testing negative for prescribed Hydrocodone altogether (December 2017) – Defendants as described above in Paragraphs 97-117 continued to issue prescriptions to D.F. for opioids and/or narcotics until he ultimately died of an overdose.

2. URINE DRUG SCREEN TESTS WERE NOT MEDICALLY NECESSARY OR SUBSTANTIATED.

153. Urine drug testing must be based on medical necessity and a complete clinical assessment of the patient's risk potential for abuse and diversion should be performed on a patient using a validated risk assessment.

154. No risk assessments were provided to support definitive (quantitative) testing performed and Defendants routinely ordered both presumptive (qualitative) and definitive (quantitative) tests together regardless of the need to do so.

155. Further, definitive (quantitative) were ordered regardless of the outcome of the presumptive (qualitative) test results despite Medicare/Medicaid regulations indicating that definitive (quantitative) testing is only reasonable and medically necessary if presumptive (qualitative) test results are inconsistent with treatment and the patient is symptomatic.

156. The drug testing that Defendants ordered were performed on-site at APC, which would have enabled Defendants and its/their providers to know the results of presumptive (qualitative) testing on the date of service.

157. If Defendants had reviewed or received the results of the presumptive (qualitative) tests prior to ordering definitive (quantitative) tests, they would have determined that definitive (quantitative) testing was not always medically necessary for most patients due to a lack of symptoms of abuse, consistent (i.e. expected) presumptive (qualitative) test results, or presumptive (qualitative) results that aligned with the patient's care plan.

158. Defendants routinely ordered/performed both presumptive (qualitative) and definitive (quantitative) urine testing together without consideration for the medical necessity of the definitive (quantitative) test.

159. From February 2018 to June 2019, Naushad and APC falsely indicated in reimbursement claims to Medicare and Medicaid using CPT and HCPCS codes 80307, 80307AR, 80307SA, G0431, G6042, G6053, G6056, G6058, G0479, G0480AR, G0480SA and G0480 that urine drug tests performed were reasonable and medically necessary for patients being prescribed controlled substances, when there was no medical necessity, and the tests were not substantiated, or were only partially substantiated when billed to Medicare and Medicaid.

160. For example, those unnecessary urine drug screening tests described in this part include, but are not limited to, the following patients:

a. G.B.

161. Defendants ordered and performed both presumptive (qualitative) and definitive (quantitative) urinalysis drug tests on G.B. on April 21, 2018 and August 8, 2018. Defendants ordered and performed the definitive (quantitative) tests simultaneously with a presumptive (qualitative) test before receiving and/or reviewing a presumptive (qualitative) test result, or a separate order for the definitive (quantitative) tests.

162. G.B.'s medical records, however, did not report any suspicion of non-compliance with his plan of care; instead, those records indicate a consistent behavior, demeanor and orientation without any proof of or documentation as to suspicions of non-compliance.

163. The definitive (quantitative) urinalysis drug tests ordered and performed were not medically necessary or substantiated when billed to Medicare.

b. M.Y.

164. Defendants ordered and performed both presumptive (qualitative) and definitive (quantitative) urinalysis drug tests on January 30, 2018; May 7, 2018; June 6, 2018; November 5, 2018; January 28, 2019; April 22, 2019 and June 27, 2019 on M.Y. Defendants ordered and performed the definitive (quantitative) tests simultaneously with a presumptive (qualitative) test before receiving and/or reviewing a presumptive (qualitative) test result, or a separate order for the definitive (quantitative) tests.

165. M.Y..'s medical record and assessments, however, did not reflect signs or symptoms of medication misuse or illicit drug use; instead, M.Y.'s previous drug test results on November 7, 2018 were consistent with prescribed medications. M.Y.'s patient records further lack any proof of or documentation as to suspicions of non-compliance.

166. The definitive (quantitative) urinalysis drug tests ordered and performed were not medically necessary or substantiated when billed to Medicare.

c. K.K.

167. Defendants ordered and performed both presumptive (qualitative) and definitive (quantitative) urinalysis drug tests on October 8, 2018, January 14, 2019 and April 8, 2019 on K.K.. Defendants ordered and performed the definitive (quantitative) tests simultaneously with a presumptive (qualitative) test before receiving and/or reviewing a presumptive (qualitative) test result, or a separate order for the definitive (quantitative) tests.

168. K.K..'s medical records, however, did not report any suspicion of non-compliance with K.K.'s plan of care; instead, those records indicate a consistent behavior, demeanor and orientation without any proof of or documentation as to suspicions of non-compliance. The notes stated there was no history of drug and alcohol abuse, side effects of narcotics or drug interactions, aberrant drug-related behavior, or lost/stolen medications or early demand.

169. The presumptive (qualitative) test results on the dates at issue were consistent with treatment and the patient record did not reflect any signs or symptoms of illicit drug use.

170. The definitive (quantitative) tests for K.K. were ordered and performed simultaneously with a presumptive (qualitative) test before Defendants received and/or reviewed a presumptive (qualitative) test result, or a separate order for the definitive (quantitative) tests.

171. The definitive (quantitative) urinalysis drug tests ordered and performed on K.K. were not medically necessary or substantiated when billed to Medicare.

172. Further, G.B., M.Y. and K.K.'s medical records did not include a patient risk assessment; did not show that the patients had histories of substance abuse or symptoms of illicit drug use; and presumptive (qualitative) urinalysis drug tests often reflected results consistent with the

patients' plan of care. Nonetheless, Defendants still routinely performed definitive (quantitative) and presumptive (qualitative) tests against Medicare/Medicaid guidelines.

173. Naushad and APC submitted false claims for presumptive (qualitative) urine drug screenings to Medicare and Medicaid which they knew were false, not used for patient care, were unsubstantiated and/or were not reasonable or medically necessary in violation of the FCA.

COUNT I:
CIVIL PENALTIES FOR UNLAWFUL DISPENSING OF CONTROLLED SUBSTANCES UNDER THE CONTROLLED SUBSTANCES ACT

174. The United States realleges the above paragraphs as if fully set forth herein.

175. Defendants knowingly prescribed controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1), and 21 C.F.R. § 1306.04.

176. As a result of the foregoing, Defendants are liable to the United States for a civil penalty not more than $80,850.00 for each violation occurring after November 2, 2015, pursuant to 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5.

COUNT II:
FALSE OR FRAUDULENT CLAIMS TO MEDICAID AND MEDICARE FOR PRESCRIPTION DRUGS IN VIOLATION OF THE FALSE CLAIMS ACT

177. The United States realleges the above paragraphs as if fully set forth herein.

178. Defendants knowingly, or with reckless disregard, presented, or caused to be presented false or fraudulent claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

179. Specifically, Defendants submitted, or caused to be submitted, claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (Medicare); and the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (Medicaid) for dispensing controlled

substances and other medications, that were invalid and not prescribed for a legitimate medical purpose.

180. Because of Defendants' acts, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the FCA, plus civil penalties of not less than $11,665 and up to $23,331 for violations that occurred after November 2, 2015. 31 U.S.C. § 3729(a); 28 C.F.R. § 85.5.

COUNT III:
FALSE OR FRAUDULENT CLAIMS TO MEDICAID AND MEDICARE FOR URINE DRUG SCREENINGS IN VIOLATION OF THE FALSE CLAIMS ACT

181. The United States realleges the above paragraphs as if fully set forth herein.

182. Defendants knowingly, or with reckless disregard, presented, or caused to be presented false or fraudulent claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

183. Specifically, Defendants submitted, or caused to be submitted, claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (Medicare); and the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (Medicaid) for diagnostic urinalysis screenings, that were invalid and not ordered for a legitimate medical purpose.

184. Because of Defendants' acts, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the FCA, plus civil penalties of not less than $11,665 and up to $23,331 for violations that occurred after November 2, 2015. 31 U.S.C. § 3729(a); 28 C.F.R. § 85.5.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests that:

A. As to Count I, judgment be entered in favor of the United States and against Defendants for civil penalties under the CSA, plus interest, costs, and any and all relief that the Court deems just and proper.

B. As to Count II, judgment be entered in favor of the United States and against Defendants for treble damages and civil penalties under the FCA, plus interest, costs, and any and all relief that the Court deems just and proper.

C. As to Count III, judgment be entered in favor of the United States and against Defendants for treble damages and civil penalties under the FCA, plus interest, costs, and any and all relief that the Court deems just and proper.

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Dated: May 31, 2024

Respectfully submitted by,

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